



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

m354117

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-50608

March 13, 2000

Frank J. Gomes  
Frank J. Gomes Dairy  
5301 North De Angelis Road  
Stevenson, California 95374-9726

**WARNING LETTER**

Dear Mr. Gomes:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 27, 2000, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On November 2, 1999, you consigned a dairy calf (identified by USDA laboratory report number 383857) to be slaughtered for human food at [REDACTED]. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of oxytetracycline in the liver at 13.00 parts per million (ppm), in the muscle at 7.10 ppm, and in the kidney at 73.00 ppm. Presently, the tolerance level for oxytetracycline in the uncooked edible tissues of cattle (Title 21 Code of Federal Regulations 556.500) is 6.0 ppm in the liver, 2.0 ppm in the muscle, and 12 ppm in the kidney.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

You lack an adequate system for determining the medication status of animals you offer for slaughter.

You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Oxy-Mycin 100 brand oxytetracycline within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with approved labeling. Labeling directions prescribed by your veterinarian specify that cattle in which oxytetracycline has been administered must be withheld for twenty-two days prior to slaughter. Treating calves with oxytetracycline just prior to sending them to slaughter is not in conformance with prescribed labeling, and is likely the cause of the illegal residues found in the animal you consigned for slaughter.

Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be sold at an auction where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use, which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of January 3, 1991, through November 2, 1999, your firm sold eight dairy animals, which were found to contain illegal drug residues. During this same period you sold two calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. The State of California conducted two inspections of your dairy on February 2, 1992, and on May 12, 1995. The Food & Drug Administration conducted an inspection of your dairy on June 21 and 22, 1994. During

these inspections you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated September 23, 1994, was sent to you as a result of the violations found during the Food & Drug Administration inspection. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made.

Please direct your reply to Suzanne Schenck, Compliance Officer.

Sincerely yours,



District Director  
San Francisco District

cc:

